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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,041	06/12/2007	Ashok Kumar Gupta	U 016370-1	7898
140 LADAS & PARRY LLP 26 WEST 61ST STREET NEW YORK, NY 10023	7590 08/19/2010		<div>EXAMINER</div> <div>CUTLIF, YATE KAI RENE</div> <div>ART UNIT</div> <div>PAPER NUMBER</div> <div>1621</div> <div>NOTIFICATION DATE</div> <div>DELIVERY MODE</div> <div>08/19/2010</div> <div>ELECTRONIC</div>	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nyuspatactions@ladas.com

Office Action Summary

Application No.

10/585,041

Applicant(s)

GUPTA ET AL.

Examiner

YATE' K. CUTLIFF

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 6, 7 & 9 - 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6, 7 & 9 - 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Interval Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Status of Claims

1. Claims 1, 2, 6, 7 and 9 - 12 are pending.
Claims 3, 4, 5 and 8 have been canceled
Claims 1, 2, 6, 7 and 9 - 12 are rejected.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 6, 2010 has been entered.

Response to Arguments

3. Applicant's arguments, see pages 5 - 7, filed May 17, 2010 and entered July 6, 2010, with respect to the rejection(s) of claim(s) 1, 2, 6, 7 and 9 - 12, claims 3 and 8 having been cancelled, under 35 USC 103(a) have been fully considered and are persuasive because of the claim amendments and arguments. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of 35 USC 112, first paragraph as set out below.

Claim Rejections - 35 USC § 112 (New Matter)

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 1, 2, 6, 7 and 9 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the proscription against the introduction of new matter in a patent application (35 U.S.C. 132 and 251) serves to prevent an applicant from adding information that goes beyond the subject matter originally filed. See *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981). Further, that the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads). The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc.*, 935 F.2d at 1563-64, 19 USPQ2d at 1117.

Claim 1; line 3 recites the phrase "edible or non-edible oils".

The Examiner can not find support for this limitation in the body of the originally filed Application.

Claim Rejections - 35 USC § 112 (Scope of Enablement)

6. Claims 1, 2, 6, 7 and 9 – 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of an organometallic catalytic compound of tin where in the compound is dioctyltin oxide, does not reasonably provide enablement for any and all organometallic catalytic compounds containing tin, i.e. (bis)tributyltin oxide, (bis)tripropyltin oxide or tributyltin chloride. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The test for enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (United States v. Teletronice, 8, USPQ2D 1217 (Fed. Cir, 1988). Whether undue experimentation is needed is not based upon a single factor but rather in a conclusion reached by weighing many factors. The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in *Wands* states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8

USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention.

"Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a process for preparing fatty acid alkyl esters from fatty acid glycerides selected from the group consisting of vegetable oils, edible or non-edible oils containing high free fatty acid, animal oils, fats and fatty acids and mixtures thereof wherein esterification and transesterification of the triglyceride is carried out simultaneously, with the catalyst being an organometallic catalytic compound of tin. Thus, the claims imply that any and all types of organometallic catalyst containing tin (organotin compounds) are useful in the claimed process of preparing fatty acid alkyl esters from a vegetable oil.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

The state of the art of organotin compounds that there are plurality of organotin compounds that can be used as catalytic agents, the compounds being classified as mono, di, tri or tetraorganotins depending on the number of organic chains present. They have the general formula of R_mSnX_{4-m} , where $m=1-4$, R = alkyl or aryl and X = halogen, -OH, -SH, OR'... . Examples of the organotin compound forms are disclosed in Table 1, page 68 Figure 1, Table 3, Table 4, Table 5 and Table 6 of Piver.

The predictability or unpredictability of the chemical arts is that chemistry is unpredictable. See *In re Marzocchi and Horton*, 169 USPQ 367. Further, as stated in a recent treatise:

"Most non-chemists would probably be horrified if they were to learn how many attempted syntheses fail, and how inefficient research chemists are. The ratio of successful to unsuccessful chemical experiments in a normal research laboratory is far below unity, and synthetic research chemists, in the same way as most scientists, spend most of their time working out what went wrong, and why. Despite the many pitfalls lurking in organic synthesis, most organic chemistry textbooks and research articles do give the impression that organic reactions just proceed smoothly and that the total synthesis of complex natural products, for instance, is maybe a labor-intensive but otherwise undemanding task. In fact, most syntheses of structurally complex natural products are the result of several years of hard work by a team of chemists, with almost every step requiring careful optimization. The final synthesis usually looks quite different from that originally planned, because of unexpected difficulties encountered in the initially chosen synthetic sequence. Only the seasoned practitioner who has experienced for himself the many failures and frustrations which the development (sometimes even the repetition) of a synthesis usually implies will be able to appraise such work Chemists tend not to publish negative results, because these are, as opposed to positive results, never definite (and far too copious) [preface] even structurally simple compounds often turn out not to be so easy to make as initially

thought. [pg. 2] As illustrated by the examples discussed below, a good retrosynthesis requires much synthetic experience, a broad knowledge of chemical reactivity, and the ability to rapidly recognize synthetically accessible substructures [pg. 3] As will be shown throughout this book, the outcome of organic reactions is highly dependent on all structural features of a given starting material, and unexpected products may readily be formed. [8] Even the most experienced chemist will not be able to foresee all potential pitfalls of a synthesis, specially so if multifunctional, structurally complex intermediates must be prepared. The close proximity or conformational fixation of functional groups in a large molecule can alter their reactivity to such an extent that even simple chemical transformations can no longer be performed. Small structural variations of polyfunctional substrates might, therefore, bring about an unforeseeable change in reactivity [pg. 9] "Dorwald F. A. Side Reactions in Organic Synthesis', 2005, Wiley: VCH, Weinheim pg. IX of Preface (cited on the IDS) and pg. 1-15.

(5) The relative skill of those in the art:

One of ordinary skill is a practicing organic chemist.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for the use of diocetyl tin oxide as a catalyst.

However, the specification does not provide support or examples of the claimed process for preparing fatty acid alkyl esters from fatty acid glycerides selected from the group consisting of vegetable oils, edible or non-edible oils containing high free fatty acid, animal oils, fats and fatty acids and mixtures thereof wherein esterification and transesterification of the triglyceride being carried out simultaneously, with the catalyst

being a organometallic catalytic compound of tin of any of the other known organotin compounds, such as those set out in the prior art of Piver.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the numerous organotin compounds known in the art at the time of Applicant's claimed process and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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